228.1006

**UNITED STATES PATENT & TRADEMARK OFFICE**

Re: Application of: Wolfgang FLEISCHER and Karin REIMER

Serial No.: To Be Assigned

Filed: Simultaneously Herewith

For: **PREPARATIONS FOR THE APPLICATION OF ANTI-INFLAMMATORY, ESPECIALLY ANTISEPTIC AGENTS AND/OR AGENTS PROMOTING THE HEALING OF WOUNDS, TO THE UPPER RESPIRATORY TRACT AND/OR THE EAR**



**LETTER RE: PRIORITY**

Box: PCT
Assistant Commissioner for Patents
Washington, D.C. 20231

November 27, 2000

Sir:

Applicants hereby claim priority from United States Application No. 60/086,895 filed May 27, 1998.

Respectfully submitted,

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09/701220

REC'D 25 AUG 1999
WIPO PCT

PA 108103

# THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office

EP99/3677 June 08, 1999

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: *60/086,895*
FILING DATE: *May 27, 1998*

**PRIORITY DOCUMENT**
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By Authority of the
COMMISSIONER OF PATENTS AND TRADEMARKS

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Atty. Docket No.: P62107US0

Assistant Commissioner of Patents
Washington, D.C. 20231

Sir:

Transmitted herewith for filing is a **PROVISIONAL APPLICATION** of

**Dr. Wolfgang FLEISCHER** residing at
**Posener Strasse 6, D-55218 Ingelheim, GERMANY**
-and-
**Dr. Karen REIMER** residing at
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for **POVIDONE IODINE FOR THE ADMINISTRATION VIA THE UPPER AND LOWER RESPIRATORY TRACT.** The application comprises a 5-page specification, including 5 claims and Abstract.

Accompanying this application for filing is:
_X_ Filing Fee: Small Entity, $75.00 X Large Entity, $150.00

Check No. 37756 , in the amount of $ 150.00, is enclosed to cover the Filing Fee. The Commissioner is hereby authorized to charge payment of any fees set forth in §§1.16 or 1.17 during the pendency of this application, or credit any overpayment, to Deposit Account No. 06-1358. A duplicate copy of this sheet is enclosed.

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Respectfully submitted,

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By William E Player
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# Povidone iodine for the administration via the upper and lower respiratory tract



The invention is concerned with the use of povidone iodine for administration via the upper and/or lower respiratory tract.

Povidone iodine is an antiseptic agent which is known for the topical treatment of infectious maladies. Also antibiotic agents are used for treatment of infectious diseases. A decisive disadvantage of antibiotic agents is that resistances are established, furthermore, antibiotics may sensitize the patients so that they develop allergies against such agents. Polividone iodine or PVP iodine, i. e. poly(1-vinyl-2-pyrrolidine-2-one)-iodine complex is an antiseptic agent which does not cause resistances of the infectious agents against that particular compound.

At present, infectious diseases of the respiratory tract are treated with antibiotics. This leads to the complications which are known to the skilled person. For example, patients suffering from chronical bronchitis are often treated with antibiotics in order to alleviate the symptoms. However, this

often merely leads to resistances of the bacteria which are responsible for the symptoms. Such patients are not cured from the infections.

It is one object of the present invention to avoid the drawbacks of the treatment of the respiratory tract using antibiotics.

Surprisingly, the use of povidone iodine into the upper and/or lower respiratory tract is able to treat diseases which are susceptible to the administration of povidone iodine via the upper and/or lower respiratory tract.

Preferably, the povidone iodine is prepared in form of a liposome preparation, in form of a microsphere preparation and/or in form of nanoparticle preparation.

The povidone iodine preparation can be administered to the respiratory tract by nebulization of the liposome, microsphere or nanoparticle preparation or by dry powder inhalation of the respective preparation. For example, a liposome preparation can be made by loading liposomes with PVP iodine in a conventional procedure. The nature or constitution of the liposomes are not critical. The liposome preparation as, for example, described in EP-A-0 639 373 A1 can be administered by inhalation of an aerosol. The disclosure of EP-A-0 639 373 is incorporated by reference. It is also possible to press the loaded liposomes, optionally together with auxiliary material such as low molecular sugars, preferably lactose, to a tightly compacted solid medicament stock. This medicament stock can then be abraded or micronized or treated in another way to yield the powder in particle form. Preferably, the particle sizes are in the range of 0.1 to 50 µm if inhaled to the lower respiratory tract or 1 to 50 µm when applied through nasal application.

The pressure for preparing the tightly compacted solid medicament stock are preferably in the range of from 50 to 500 MPa. Such medicament stock is described in WO 94/14490 and in device for administration is disclosed in WO 93/24165. The disclosure of WO 94/14490 and WO 93/24165 are incorporated by reference.

Instead of liposome preparations, it is also possible to associate the povidone iodine with nanoparticles or microspheres.

The present invention is useful in the treatment of infectious diseases or for alleviation of diseases such as HIV infections which are accompanied with opportunistic infections. Also patients having a suppressed immune system, for example, after organ transplants, can be treated according to the invention. In particular, acute and chronical bronchitis, pneumonia, bronchiectasia, cystic fibrosis, diphtheria, tuberculosis can be treated with the povidone iodine preparation according to the invention.

## Claims

1. Use of povidone iodine for the preparation of a pharmaceutical composition for the treatment of diseases which are susceptible to the administration of povidone iodine via the upper and/or lower respiratory tract.

2. Use according to claim 1 wherein the povidone iodine is prepared in form of a liposome preparation, in form of a microsphere preparation and/or in form of a nano particle preparation.

3. Use according to claim 1 and/or 2 wherein the administration of the povidone iodine preparation into the respiratory tract is performed by aerosol nebulization or by dry powder inhalation.

4. Use according to claim 1 for the treatment of infectious diseases or alleviation of diseases such as HIV-infections which are accompanied with opportunistic infections or with a suppressed immune system.

5. Use according to claim 1 for the treatment of acute and chronic bronchitis, pneumonia, bronchiectasia, cystic fibrosis, diphtheria, and/or tuberculosis.

## Abstract

Use of povidone iodine for the preparation of a pharmaceutical composition for the treatment of diseases which are susceptible to the administration of povidone iodine via the upper and/or lower respiratory tract.